APR 2 6 2001

K010955

510(k) Summary for Boston Medical Technologies, Inc. (BMT)
Anscore™ Health Management System ("Anscore™")

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

The submitter of this premarket notification is:
Cesidio Tempesta
Manager of Regulatory Affairs/Quality Assurance
Boston Medical Technologies, Inc
591 North Avenue, Suite 5
Wakefield, MA
Tel: 781.213.9200, Fax: 781.213.9233

This summary was prepared on March 6, 2001.

The name of this device is the Anscore™ System. The common name is ECG monitor and Respiration Pacer. Classification names are as follows:

Regulation Number	Classification Name
870.2340 - 74 DPS, II	Electrocardiograph

The Anscore™ System is substantially equivalent to the to the previously 510(k)-cleared Anscore™ Health Management System (K993875).

Description: The Anscore™ System is a cart-based system with a computer- based user interface and data acquisition system for testing, data collection and data transmission for remote processing. The device features a 3 lead ECG, an optional blood pressure monitor, and a breathing apparatus.

Intended use: The Anscore™ System has the same intended use as the legally marketed predicate devices. When used in the physician office or hospital environment, the Anscore™ system is intended for use in heart rate variability (HRV) measurements in response to paced respiration and controlled exercises.

The Anscore™ Health Management System reflects Normal Range Limits as defined in clinical data collected with the device. The predicate device was originally cleared (K991831) reflecting Lower Range Limits as defined in referenced literature. These device specific limits are appropriate, since the method of testing and controls applied using the Anscore™ HMS are consistent and repeatable from test to test, and may not reflect the requirements and controls employed in the earlier studies. The change in reported Normal Ranges does not raise new safety and effectiveness issues because the manner in which the system collects and records physiological data, and then reports the derived ratios has not changed. The age specific Normal Range limits are displayed on the final printed reports for the physician's reference.

Technological characteristics: The Anscore™ System with specific Normal ranges is technologically identical to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2001

Mr. Cesidio Tempesta
Boston Medical Technologies, Inc.
591 North Avenue, Suite 5
Wakefield, MA 01880-1641

Re: K010955
Trade/Device Name: Anscore ™ Health Management System
Regulatory Class: II (two)
Product Code: DPS
Dated: March 2, 2001
Received: March 30, 2001

Dear Mr. Tempesta:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known) K010955

Device Name The ANScore™ System

Indications for Use The Anscore™ system is intended for use in heart rate variability (HRV) measurements in response to paced respiration and controlled exercises.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices

510(k) Number K010955

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)